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Performance evaluation of a novel piezoelectric subcutaneous bone conduction device

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Performance evaluation of a novel piezoelectric subcutaneous bone conduction device

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Abstract

Objectives: Evaluation of the transfer function efficiency of a newly-developed piezo-electric actuator for active subcutaneous bone conduction hearing aid.

Methods: The experiments were conducted on four Thiel embalmed whole head cadaver specimens. A novel actuator based on piezo-electric transduction (PZTA), part of a subcutaneous bone conduction hearing aid device, was sequentially implanted on three locations: 1) Immediately posterior to pinna; 2) 50-60mm posterior to pinna, approximately the same distance as between the BAHA (bone anchored hearing aid) location and the ear canal, but the same horizontal level as location 1; 3) the traditional BAHA location. Using a single point 3-dimensional laser Doppler vibrometer (LDV) system, three types of motion measurements were performed at the cochlear promontory for each stimulation location: 1) ipsilateral side, 2) contralateral side, 3) measurements 1 and 2 were repeated after mastoidectomy on the ipsilateral side.

Results: On average, stimulation at locations 1 and 2 show a trend for higher promontory motion relative to location 3 (BAHA location) above 1 kHz. Stimulation at location 1 had an average improvement of 1 to 6 dB at 2-4 kHz, and 1 to 18 dB at 6-8kHz. The spatial composition of the motion showed significant contributions from both in-plane and out-of-plane (along ear canal) motion components, with in-plane components being dominant at mid and high frequencies for locations 2 and 3. Stimulation at locations 1 and 3 produced similar transcranial attenuation at mid frequencies (0.6-4kHz), with a potential trend of higher attenuation (seen in 3 or the 4 samples) for location 1 at higher frequencies (>4kHz). The mastoidectomy affected negatively mostly the high frequencies (6-8 kHz) for stimulation at location 1, with no significant change for location 3.

Conclusion: The sound transfer function efficacy of a novel subcutaneous bone conduction device has been quantified, and the influence of stimulation location and mastoidectomy have been analyzed based on promontory motion in Thiel-preserved cadaver heads.

Keywords: Bone conduction, Laser Doppler Vibrometer, cadaver head, piezoelectric actuator, bone conduction hearing aid, mastoidectomy, transcranial attenuation.

1 Introduction

Bone conduction (BC) is defined as the conduction of sound from the source (sound waves in air or actuator in contact with the head) to the inner ear through mechanical vibrations of structures of the head and body (bones, soft-tissue, liquids, etc.). BC is an alternative to air conduction (AC) to stimulate the cochlea and generate a sound perception. Due to the variety of structures of the head involved in bone conduction, several possible pathways have been suggested in the literature as possibilities for the transmission of vibrational energy from the stimulator to the cochlea (Stenfelt and Goode, 2005a). Since some of the possible BC pathways are independent of the state of the middle ear, BC can be used as an alternative to AC in case of disruption of the sound transmission function of the middle ear. Clinically this is applied in patients with single-sided deafness, or with a conductive hearing loss, who cannot benefit from a conventional hearing aid but can benefit from BC stimulation via a bone conduction hearing aid (BCHA) (Pfiffner et al. 2011). An optimal coupling of the BCHA aims at providing a sufficiently efficient transfer of the sound energy from the device's actuator, through the head structures, and into the cochlea. However, the coupling mechanism between a BCHA device and the skull bone or skin has not been completely understood due to its complexity. In addition, various devices, with different attachment techniques, have been proposed or are under development. They can be divided into devices that provide BC stimulation via the skin (transcutaneous), and devices that directly stimulate the bone (percutaneous), as shown in Fig. 1 (Håkansson et al., 1985, 1986 and 2008).

For devices that stimulate the skull through the skin, the actuator is pushed against the skin via tension provided by their corresponding support system. For spring-like support, this includes hearing glasses and BCHA that are held at the stimulation location by a softband or a metal spring (i.e. Baha® on a steel band). The contact force between the actuator and the skin could also be generated magnetically, as is the case with BCHA that use an implanted magnet, which holds the actuator over the intact skin (transcutaneous devices) (i.e. Sophono™ Alpha, Medtronic, FL, USA; and Baha® Attract, Cochlear® BAS, Mölnlycke, Sweden). However, such devices require a surgical procedure for the implantation of a percutaneous implant (without titanium abutment) to anchor the magnet to the skull. Instead via tension, the actuator could be temporarily attached to the skin via specially designed adhesive pad (ADHEAR Bone Conduction System, Med-El, Innsbruck, Austria), allowing for surgery free and inconspicuous attachment of the BCHA.

The second group of BCHA includes devices that is in direct contact with a bony part of the head. One subgroup of such devices uses a percutaneous implant (BI300, Cochlear® BAS, Mölnlycke, Sweden) attached to the skull, such that the actuator is attached on the implant, above the skin (Baha® Cordelle II, Cochlear® BAS, Mölnlycke, Sweden). The second subgroup of devices, with direct stimulation on a bony area, are ones that stimulate the teeth (SoundBite ™, Sonitus Medical, CA, USA), which in turn excites the skull bone. A third subgroup consists of devices that leave the skin intact, by having driving electronics and actuators fully implanted subcutaneously. Typically, the implantable actuators are installed via a surgical procedure that creates a bone bed (recess) into the skull bone with 4-9mm depth, depending on the device and anatomy, within which the body of the actuator is laid and secured with wire or screws (BC-FMT transducer of the Bonebridge™ system from MED-EL, Innsbruck, Austria; bridging bone conductor of Håkansson et al., 2010). Such a procedure is more complicated than the implantation of BI300 (without abutment) and could be a limiting factor in the application of such devices. In addition, the surgical procedure requires a minimum skull thickness in the area of the implantation of the actuator, which might not be available in all patients due to young age or specific anatomical features. On the other hand, while solutions providing stimulation on skin require minimal (magnet implantation) or no surgical intervention (softband, adhesive pad), they typically provide reduced sound transmission capabilities (coupling efficacy) compared to the systems with direct bone stimulation (Håkansson et al., 1985, 1986 and 2008).

There are several important aspects when testing and optimizing a new or existing BCHA, regardless of its means of attachment to the head, some of which are: 1) dependence on stimulation location; 2) resultant transcranial attenuation; 3) dependence on any bone conduction related pre-existing conditions, such as mastoidectomy. The stimulation location could strongly influence the resultant BC hearing sensation, while also affecting the surgical complexity of implantation of the device. Thus, many studies have been conducted on the topic of stimulation location, including, but not limited to, studies on cadaver heads (Dobrev et al., 2016; Stenfelt and Goode, 2005b), patients (Stenfelt, 2012), and comparison between clinical and laboratory measurements (Eeg-Olofsson et al., 2013; Reinfeldt et al., 2014). Transcranial attenuation could strongly influence the efficiency of a BCHA in the case of single sided deafness (SSD), when the device is used to transmit sound from deaf side to the normal hearing side, or in the case of BC hearing assessment tests. Thus, a large number of studies have explored this issue (Dobrev and Sim, 2018; Eeg-Olofsson et al. 2011b; Reinfeldt et al., 2014; Stenfelt and Goode, 2005b). In the case of mastoidectomy, the bone conduction transmission properties of the skull, and the temporal bone in particular, could be altered, which have also been investigated (Kim et al., 2010).

A new type of recently developed BCHA could provide a balance between surgical complexity and coupling efficacy. A novel subcutaneous bone conduction device based on piezo-electric transduction (PZTA) actuator (Patent WO2009121116A1, Applicant: Cochlear® BAS, Mölnlycke, Sweden) has a fully implantable actuator and driving electronics, similar to other implantable active devices. However, the mechanical connection (center area of the PZTA) to the skull bone is via an implant (i.e. BI300, without the titanium abutment), similar to the way the implanted magnet devices (i.e. Baha Connect ®, Cochlear® BAS, Mölnlycke, Sweden) are attached, requiring no bone bed drilling. This potentially provides the sound coupling benefits from direct contact with the skull, but with less strict requirement on the available bone thickness in the implantation area and simpler implantation procedure. An PZTA prototype is show in Figure 2, where it is visually compared to a Baha® Cordelle II (Cochlear® BAS, Mölnlycke, Sweden).

In order to define a surgical implantation procedure, an optimal stimulation location for the PZTA is needed. There have been numerous studies quantifying the dependence of the promontory motion (in cadaver heads), skin or skull impedance (in cadaver heads and patients), and BC hearing sensation (in patients) on the stimulation location of a BCHA actuator (Eeg-Olofsson et al., 2008; Eeg-Olofsson et al., 2011a;

Eeg-Olofsson et al., 2011b; Eeg-Olofsson et al., 2013; Reinfeldt et al., 2014; Dobrev et al.,2016). However, in most of these studies the actuator is situated above the skin, where vibrations of the actuator's body are not directly affected by the skin and soft tissue properties. In addition, the existing actuators' shapes and implantation procedures differ from the PZTA. In the case of the PZTA, while the device attaches to the BI300 at a single point, the whole body of the device could be vibrating during operation, similar to other implantable actuators (BC-FMT transducer of the Bonebridge™ system from MED-EL, Innsbruck, Austria; bridging bone conductor of Håkansson et al., 2010). In addition, the actuator's body could be in contact with the skull bone at other points than the BI300, due to the local topology of the skull under the actuator's body. This means that the output performance could be partially dependent on the mechanical parameters of the surrounding soft tissue (damping, effective mass, etc.) and skull surface. In other to evaluate the combined effect of such variations on the output of the PZTA, and the resultant promontory motion or hearing sensation, additional experimental work is needed.

This study is focused on the testing of the sound transfer efficacy of a PZTA on Thiel preserved cadaver heads (Thiel, 1992; Guignard et al., 2013). The PZTA is part of a novel subcutaneous bone conduction device currently under development by Cochlea Bone Anchored Solutions (Cochlear® BAS, Mölnlycke, Sweden). The sound transfer efficiency was defined as the ratio between the cochlea promontory motion and the input voltage to the actuator, for two sets of test conditions: 1) varying the stimulation location (Dobrev et al., 2016; Egg-Olofsson et al., 2011); and 2) repeating set 1) after a mastoidectomy near the ear canal of the ipsi-lateral ear. For each test condition, the full vibrational motion, consisting of all 3 orthogonal components of acceleration, was quantified via 3-dimensional laser Doppler vibrometry (3D LDV) methods (Dobrev and Sim, 2018). For each test condition both ipsi- and contra-lateral promontories were measured and the corresponding transcranial attenuation was calculated.

2 Methods

This study was approved by the Ethical Committee of Zurich (KEK-ZH-Nr. 2012-0136).

2.1 Sample preparation

The experiments were conducted on four Thiel embalmed (Thiel, 1992; Guignard et al., 2013) whole head cadaver specimens. The performance of the PZTA under each measurement condition was evaluated based on the resultant promontory motion, since it is an accepted estimator for the resultant hearing sensation (Eeg-Olofsson et al., 2013; Stenfelt, 2015). In order to provide optical access to the promontory for the vibration measurements, an endaural incision was made between ascending helix and tragus, and a tympanomeatal flap was elevated to expose the promontory on both sides of the head. The measurement point at each promontory, located within approximately 1-3mm from the round window, was covered with either a 1-2 mm^2 retro-reflective sticker (DG3 4000, 3M, MN, USA) or retro-reflective spheres (30-100μm in diameter, P2453BTA-4.2 30-100um, Cospheric LLC, CA, USA) glued to the promontory surface with cyanoacrylate glue (57040-00000, tesa SE, Norderstedt, Germany). The choice of retro-reflector type for each cadaver head was based on the specific anatomy and condition of the promontory wall in each sample. Before application of the retro-reflector, the promontory area was cleaned of fat and soft tissue, and carefully dried with cotton. The head orientation relative to the measurement system was consistent for all samples, such that the ipsilateral side was always the right side of the heads.

The following stimulation locations were under investigation (also shown in Fig. 3 A): 1) Immediately posterior to pinna, equivalent to location B in Reinfeldt et al. (2014); 2) 50-60mm posterior to pinna, approximately the same distance as between the BAHA location and the ear canal, but the same horizontal level as location 1; 3) the traditional BAHA location. The reason for considering location 1 was that it could provide stronger stimulation to the cochlear relative to the other two locations, due to its proximity to the inner ear. Location 2 was chosen because of it being further away from the ear canal, thus alleviating potential problems with implantation in the proximity of the pinna or in the proximity of a mastoidectomy, while providing attachment to the firmer bone at the base of the skull relative to the thinner sections at location 3.

At each stimulation location, shown in Fig. 3A, a titanium implant (BI300) was implanted in the bone, through a percutaneous opening (slit) of 2-3 cm at the implant location. The attachment between the PZTA and the BI300 is similar to that of the subcutaneous magnet in the Baha Attract system. In this way the PZTA is suspended by the BI300 above the surface of the bony skull. The PZTA was inserted through the skin opening and attached to the implant. After attachment of the PZTA, the opening in the skin was sutured, and ultrasound coupling gel (any brand commonly found in hospitals, e.g., Skintact© Ultrasonic gel) was injected subcutaneously filling the gaps between the PZTA body, the skull surface, and the skin. The ultrasound gel was added based on guidelines from the manufacturer, and relevant discussions are presented in section 4.2. For each implantation, the total amount of gel deposited around the PZTA was approximately 2ml, depending on the individual anatomy.

After measurement at the ipsi- and contralateral promontory, for stimulation at each of the 3 locations, a mastoidectomy was performed and all measurements (at all stimulation locations) were repeated. An anterior mastoidectomy (Fisch et al., 2010) was performed by identifying the dura of the middle cranial fossa. The dura was then followed to the antrum and the incus, and the lateral and posterior semicircular canal were identified. Then, the digastric ridge was exposed, and the facial nerve skeletonized in its mastoid segment. The posterior canal wall was thinned out, but left intact, whereas the sigmoid sinus remained covered by bone.

2.2 Measurement setup

For each stimulation location, the motions of both the ipsi- and contra-lateral promontories were measured sequentially, by moving the 3D LDV in a repetitive manner via a robotic arm (Dobrev et al., 2017). The cadaver heads were oriented in a natural upright position, as shown in Fig. 3 B, such that most of the weight was supported by the spine, which in turn was stabilized with a short metal rod (12 mm diameter stainless steel) inserted in the spinal column of the last few inferior vertebrae of the remaining spine (~5cm corresponding to 2 vertebrae). As a means to provide additional support (i.e., against tipping of the head) and to prevent potential orientational drift during a full measurement session (i.e. 4-6 hours), the cadaver heads were also gently supported around the scalp via a softband connected, via rubber bands (< 1N per band), to 4 stiff metal rods (12-20 mm diameter stainless steel), providing only gentle (< 2-4N total) lateral support. The scalp support rod was attached to a 5-kg support plate (cast iron), and a silicone donut-shaped neck support was placed between the inferior end of the neck and the spline support plate, providing support against accidental sliding, laterally, during manipulation of the head. The head and spine support together sat in a water basin to catch any potential liquid leakage from the head. The head, the basin, and the lateral support rods were all attached to a base plate (10-kg aluminum plate), which held the whole head support assembly together. In between any two hard surfaces (i.e., metal, plastic, bone) there were Sorbothane legs or sheets installed to reduce potential rattling, which could induce distortions in the measured vibrational responses. The full assembly of the head holder was supported by vibration isolation legs (Sorbothane legs, AV3, Thorlabs Inc., NJ, USA), placed on top of a vibration isolation table (M-INT1-36-6-A, Newport Corp., CA, USA) to minimize random vibrations from external sources. The overall aim of the head holder was to mimic the natural orientation and support of the human head, specifically at lower frequencies (below 1 kHz), since previous work (Hoyer and Dortheide, 1983; McKnight et al., 2013; Dobrev et al., 2017) have indicated that cadaver head motion at such frequencies is rigid-body-like, thus heavily dependent on support (boundary) conditions.

For stimulation, an implantable PZTA, shown in Fig. 2, with a modified sound processor was used, which allowed direct electrical stimulation from a sound generator (APx585, Audio Precision Inc., USA) via an audio amplifier (RMX 850a, QSC, CA, USA). Unlike most bone conduction actuators, which are typically based on an electromagnetic type of transduction, the PZTA utilizes the piezo-electric effect. The force output part of the device was connected via its own attachment screw to a bone anchored implant (BI300, Cochlear® BAS, Mölnlycke, Sweden), visible in the center of the device in the top view in Fig. 2. The PZTA attaches to the BI300 in an equivalent way to the subcutaneous magnet BMI300 in the Baha® Attract system.

For each experimental condition, a frequency stepped sinusoidal stimulus was applied to the BC actuator at 81 logarithmically distributed frequencies in the range of

0.1-10kHz, resulting in 40 frequency points per decade. Stimulus at each frequency was presented continuously for 200ms, with a sinusoidal-shaped ramp up (onset) region of 20ms. A constant stimulation voltage of 1 Vrms was used for all frequencies. For each stimulation frequency, the promontory motion was measured using a single point 3-dimensional (3D) LDV (3D CLV 3000 by Polytec GmbH), which computes the time waveform of 3 orthogonal velocity components, from which the corresponding acceleration components are calculated. The orientation of the 3D LDV coordinate system relative to the anatomical coordinate system is indicated in Fig. 3B. The LDV's X-axis was along the posterior direction for measurements at the ipsilateral promontory and along the anterior direction for measurements at the contralateral promontory. The Z-axis was pointing laterally (away) from the promontory, and the Y-axis is always pointing in the superior direction, for both ipsi- and contra-lateral measurements.

2.3 Data processing

To reduce effects from random external disturbances, such as LDV signal drop, measurement at each frequency was repeated 5 times. Several types of quality checks were applied to each data set (5 iterations) at each frequency to determine, which data were to be further used, similar as in Dobrev et al. (2017): 1) signal-to-noise ratio (SNR) of at least 2 standard deviations above the mean noise floor in the vicinity (in the frequency domain) of each stimulus frequency (Dobrev et al., 2018); 2) amplitude repeatability within 20%, based on the complex vector difference (complex vector in the frequency domain) between any of the iterations, at a particular frequency, and the geometric average of the magnitudes of all iterations; 3) coherence of more than 0.85, where the coherence, for each iteration, is calculated for the waveform of each LDV channel and the stimulus signal. After the application of all 3 data quality criteria, the remaining data (if available) from the set of 5 iterations per frequency is reduced to 1 averaged data point (complex number) per frequency, based on the medians of the real and imaginary parts of the iterations meeting the quality criteria. Since data from 4 cadaver heads were obtained, the results for each measurement condition (stimulation location, promontory side, etc.) were averaged (using geometric mean) across heads, only for data meeting the quality criteria.

Since all 3 cartesian components of the velocity were measured, the combined velocity (and acceleration) was calculated based on methods described previously (Dobrev et al., 2017; Dobrev and Sim, 2018). Based on that, the combined velocity (and acceleration) was calculated, defined as the maximum magnitude of the complex vectoral sum of the 3 individual components (Dobrev and Sim, 2018). The combined velocity was chosen, instead of any individual motion component, since it provides a single value, instead of three, which makes analysis and interpretation simpler. In addition, from a physiological perspective, the combined velocity is indicative of the total vibratory motion, and corresponding total kinetic energy, at the measurement point (Dobrev and Sim, 2018; Stenfelt and Goode, 2005b). Because of that, the combined motion is assumed to be a better (closer to hearing sensation) representative of the perceived sound, compared to any of the individual components (Stenfelt and Goode, 2005 a and b). An advantage of the complex vectoral summation (Dobrev and Sim, 2018) is that it uses both the magnitude and phase information of each of the orthogonal components for the calculation of the combined motion, as opposed to the typically used quadratic summation (Stenfelt and Goode, 2005b) that uses only the magnitude of the orthogonal components. Using only the magnitude data could potentially overestimate the total motion when some of the motion components have a significant phase shift relative to the others (Dobrev and Sim, 2018).

Data for the driving force of the actuator was not available in our tests, thus corresponding promontory motion was normalized by the driving voltage of the PZTA. This was done for all promontory acceleration data in this work.

All post-processing, analysis and data representation was done via custom MATLAB scripts (MATLAB 2017a, MathWorks, MA, USA).

2.4 Statistical methods

Wilcoxon's signed-rank test was used in order to test the statistical significance of the differences in the promontory response due to any two measurement parameters (stimulation location, motion components, effect of mastoidectomy) within a specific frequency range. A t-test was used to estimate a confidence interval for difference between any two measurement data sets, in only those cases in which the corresponding data followed a normal distribution (when expressed as dB). The hypothesis of whether a data set followed a normal distribution was tested with a Lilliefors test (Lilliefors, 1967). All statistical tests were two-tailed. A p value of <0.05 was used as a threshold for statistical significance for all tests. Since only 4 samples were available for this study per frequency point, data at all frequencies within a specified frequency band were used for comparison, rather than at individual frequencies. This was done by averaging the response of each head across all frequencies in the particular frequency band and using that as a representative of the individual head response in the statistical tests. This was done in order to provide a more robust data (less effect of random notches) for the statistical evaluation of the significance of any potential differences, within a given frequency band of interest.

3 Results

3.1 Effect of stimulation location on ipsilateral promontory motion

The three Cartesian components of the promontory acceleration were computed from measured velocity in all 4 heads for PZTA stimulation for each location, as defined in Fig 3A. Magnitudes of the individual components and the corresponding combined motion for each stimulation location are shown in Figure 4 A-C. Included is the corresponding noise floor, averaged across samples. Data for the driving force was not available, thus measured motion data has been normalized by the driving voltage of the PZTA. Magnitudes of the individual components, normalized by the corresponding combined motion for each stimulation location, are shown in Figure 4 D-F. The aim of Figure 4 is to illustrate the differences in spatial composition (the relative contribution of each motion component) of the promontory motion, and their dependence on stimulation frequency and location.

Inter-sample variations in the promontory acceleration were mostly at the second peak (7 kHz) and mid frequencies (1- 6 kHz), with 5-10dB variation on average, relative to 5 dB average variation at frequencies below 500Hz, as seen in Figure 4 A-C. Once averaged across samples, the variation between stimulation locations showed differences in amplitude, frequency and spatial composition (relative contributions from X, Y and Z motion components). The relative contribution of the Z (along ear canal, normal to promontory) and X components (superior-anterior direction, tangent to promontory), in particular, was dependent on both frequency and stimulation location, as seen in Figure 4 D-F. At low frequencies (below 500Hz), the magnitude of the Z component was significantly larger ($p<0.05$) than the X component with a mean difference range of 2 to 12dB for stimulation location 1, 2 to 10 dB for stimulation location 2, and 3 to 14 dB for stimulation location 3 (BAHA location). At mid and high frequencies (above 500 Hz), the magnitude of the X component was significantly larger ($p<0.05$) larger than the Z component with a mean difference range of 1 to 13 dB for stimulation location 2, and 4 to 13 dB for stimulation location 3. At stimulation location 1, the magnitude of the Z component shows a tendency to be larger than the X component at mid frequencies (0.7-3 kHz), with a mean difference range of -2 to 8 dB (negative difference indicates X being larger), however there was no strong statistical significance. At higher frequencies, the two components showed very similar behavior, within ±4 dB. All ranges correspond to a 95% confidence interval, as defined in Section 2.4.

Figure 5 A shows the magnitude of the combined motion for each stimulation location, normalized by the driving voltage of the PZTA, while Figure 5 B compares the combined promontory motion for stimulation at locations 1 and 2 relative to location 3. The aim of Figure 5 was to illustrate the differences in combined promontory motion (hypothesized as related to the total sound energy), and their dependence on stimulation frequency and location, particularly differences in stimulation at locations 1 and 2 relative to location 3. On average, stimulation at locations 1 and 2 show a trend for higher promontory motion relative to location 3 (BAHA location) above 1 kHz. Stimulation at location 1 produced significantly larger ($p<0.05$) promontory motion (measured as the combined motion) than stimulation at location 3 (BAHA location), at some frequencies above 800Hz. Specifically, promontory response was 1 to 6 dB higher at 2-4 kHz, and 1 - 18 dB higher ($p<0.05$) at 6-8kHz (around the second resonance) for stimulation at location 1 relative to location 3. The inter-sample variability in the data for stimulation at location 1 in other frequency bands prevented any statistically significant conclusions. Stimulation at location 2 did not produce significantly different response relative to stimulation at location 3, below 4kHz. However, stimulation at location 2 in the 4-8kHz band produced 1 to 10 dB higher ($p<0.05$) promontory response than with stimulation at location 3.

3.2 Transcranial attenuation

The effect of stimulation location on the resultant transcranial attenuation was investigated by sequentially measuring the ipsi- and contra-lateral promontory motion, for each stimulation location. Figure 6 A shows the magnitude of the combined acceleration, normalized by driving voltage, of ipsi- and contra-lateral promontory, for stimulation at locations 1 and 3 only. Figure 6 B shows the corresponding transcranial attenuation, expressed as the ratio of magnitudes of the contralateral versus ipsilateral combined promontory accelerations, for each stimulation location. The aim of Figure 6 is to illustrate the differences in the response of the ipsi- and contralateral promontory, expressed as combined acceleration, and their dependence on stimulation frequency and location, particularly for stimulation at location 1 relative to location 3. Transcranial attenuation data for stimulation at location 2 was also available but has been omitted in this section, for purpose of brevity and because it does not change any of the presented observations or corresponding conclusions. Positive attenuation values in Figure 6 correspond to contra-lateral promontory having smaller motion than the ipsi-lateral promontory. Negative attenuation (gain) values correspond to contra-lateral promontory having larger motion than the ipsi-lateral promontory. All ranges correspond to a 95% confidence interval, as defined in Section 2.4.

Stimulation with PZTA on location 3 (BAHA location) produces transcranial attenuation in the range of -6 to -2 dB (negative attenuation corresponds to a gain) at 250 – 500 Hz, 3 to 14 dB at 2 - 4 kHz, and 2 to 9 dB above 4 kHz. In comparison, stimulation on location 1 (close to pinna) produces transcranial attenuation in the range of -7 to -4 dB (negative attenuation corresponds to a gain) 250 – 500 Hz, 2 to 17 dB at 2 - 4 kHz. In addition, above 4 kHz, there is a trend (seen in 3 of the 4 samples) for stimulation at location 1 producing stronger transcranial attenuation than at location 3, however the difference is not statistically significant.

3.3 Effect of mastoidectomy

Figure 7 shows the effect of mastoidectomy on the efficiency of the PZTA stimulation, evaluated based on the change of the ipsi-lateral promontory motion pre- and post-operatively for stimulation locations 1 and 3. The pre-mastoidectomy data are taken from data described in Section 3.2, while the post-mastoidectomy data were obtained in an equivalent manner within several days of the initial measurements. The aim of Figure 7 is to illustrate the post-mastoidectomy changes in the response of the ipsilateral promontory, expressed as combined acceleration, and their dependence on stimulation frequency and location, particularly for stimulation at location 1 relative to location 3. Post-mastoidectomy data for stimulation at location 2 was also available but has been omitted in this section, for purpose of brevity and because it does not change any of the presented observations or corresponding conclusions. In figure 7, a positive change in promontory motion, due to mastoidectomy, corresponds to increase in promontory motion, and vice versa. All ranges correspond to a 95% confidence interval, as defined in Section 2.4.

The mastoidectomy significantly ($p<0.05$) changed the promontory motion for stimulation with PZTA on location 1 (close to pinna) in the range of 2 to 5 dB at 0.5 - 2 kHz. Data for location 1 at higher frequencies showed high variability, however this was due to one of the 4 heads, which showed a drastically higher (>20dB) response than the other 3 heads. When this head is omitted from the statistical calculations, there is a statistically strong ($p<0.01$) drop in the promontory motion in the range -10 to -21dB at 6-8 kHz (around the second peak). In contrast, mastoidectomy did not produce a statistically significant ($p<0.05$) change in the promontory motion for stimulation on location 3 (BAHA location) in any of the considered frequency ranges. A positive change in promontory motion, due to mastoidectomy, corresponds to increase in promontory motion, and vice versa. The magnitude of the promontory motion, after mastoidectomy, at high frequencies (above 4kHz) becomes similar between stimulation locations 1 and 3, with mean difference of within 0.3 ± 11 dB.

4 Discussion

4.1 Samples and preparation

Thiel-reserved samples and long- term stability

Thiel embalmed heads were used, instead of fresh frozen cadaver heads because of the total measurement duration per head. Because of time and scheduling constrains, a full set of measurements in each head took 1-3 weeks, which was deemed too long to confidently assume sufficiently consistent material properties of the soft tissues after defrosting of a fresh head. Thus, Thiel embalmed heads were chosen as a test model (instead of fresh frozen cadaver heads) in order to reduce potential effects of soft tissue deterioration after thawing on the coupling of the PZTA, since it was covered by skin. Previous work (Guignard et al., 2013) on Thiel-preserved temporal bones has indicated that long-term (4-16 weeks) variation in promontory motion and skull response is approximately 3-5dB on average across 0.1-10kHz, and up to 3-7dB at 3-8kHz, while short-term repeatability (2h) is 1-2 dB on average for all frequencies. Based on these variability estimates (each based on less than 4 samples) the test schedule for this study was organized such that the measurement time per measurement condition was reduced. For example, measurements of variation of stimulation position or transcranial attenuation were done together within 1 day. Based on that, it is assumed that for tests on position variation and transcranial attenuation, differences of less than 2 dB should be not be considered significant regardless of statistical tests output. However, measurements before and after mastoidectomy, compared in Fit. 7, were separated by one week. In this case, changes below 5dB (< 7 dB at 3 – 8 kHz) should not be considered significant.

Effect of soft-tissue and ultrasound gel around the PZTA

While the PZTA attaches to the BI300 at a single point, the whole body of the device could be vibrating during operation, similar to other implantable actuators (BC-

FMT transducer of the Bonebridge™ system from MED-EL, Innsbruck, Austria; bridging bone conductor of Håkansson et al., 2010). This means that the output performance could be partially dependent on the mechanical parameters of the surrounding soft tissue (damping, effective mass, etc.). However, when implanted in cadaver heads, there could be an empty space (air gap or air pocket) between the PZTA's body and the skull or skin, which could influence its output. As per guidelines from the manufacturer for testing in cadaver heads, ultrasound gel in order reduce the possibility of air gaps, and better mimic the loading of soft tissue on the PZTA's body. However, these assumptions have not been quantitatively evaluated or controlled in the current study, except for our best efforts to adhere to consistent procedures for implantation in all cadaver heads.

Previous work (Guignard et al., 2013) have indicated that there could be significant differences in the dynamic response of soft-tissue between fresh and Thiel-preserved samples. Since contact with soft-tissue surrounding the PZTA's body could influence the output of the actuator, there may be differences between the results of this study and behavior in patients.

4.2 3D promontory motion measurements

To evaluate the potential differences in the resultant hearing sensation from stimulation at the 3 different locations, the promontory motion was measured at a location close to the round window. It has been shown before that promontory motion can be used as an acceptable estimator of BC hearing sensation (Stenfelt and Goode 2005a; Eeg-Olofsson et al., 2008; Eeg-Olofsson et al., 2013; Dobrev and Sim, 2018; Stenfelt et al., 2004), specifically at frequencies above the first few resonance frequencies of the skull (above 0.8-1kHz) (Eeg-Olofsson et al., 2013). Previous studies have shown no significant dependence of the measured cochlea motion on the measurement location, based on comparisons of motions of the promontory and the otic capsule of the lateral semicircular canal in patients (Eeg-Olofsson et al., 2013).

In order to estimate the repeatability of the promontory measurements, during a preliminary test session, both the measurement location and surface conditions under the retro-reflector were varied, while keeping all other experimental conditions constant. It was found that most of the detectable (>0.5-1dB) variations in the velocity measurements at the promontory could be reduced by careful treatment of the bony surface of the promontory. This included removing all soft tissue and moisture from the surface before installing (i.e., gluing) the retro-reflector medium. Without such treatment, various measurement artifacts were encountered such as random narrow notches in the frequency response or rapid random variations in the LDV signal level, which in turn deteriorated the SNR.

Overall, the SNR of all promontory motion presented in this work deteriorated with decreasing frequency below 0.65 kHz, as seen in Figure 4 A-C (dashed lines). This could be explained by the decreased response of the promontory at low frequencies due to the higher mechanical impedance of the skull (Stenfelt and Goode, 2005b) resulting in less motion per unit of input force, provided by the PZTA. At such low frequencies the whole head moves with very little relative deformation, similar to a single rigid body, which in turn applies larger fraction of the total mass of the head to the actuator. This behavior contrasts with the behavior at mid and high frequencies, where the head undergoes local deformations (Hoyer and Dortheide, 1983; McKnight et al., 2013; Dobrev et al., 2017), resulting in a lower effective mass applied at the actuator, thus more motion is produced per unit of input force from the actuator. In addition to the lower motion, the 3D LDV system utilized measures 3D motion based on the triangulation from 3 individual measurement laser beams, each providing information along a different sensitivity direction. The angular separation between the beams defines the relative sensitivity to in-plane (along the X-Y plane) and out-of-plane (along the Z axis) motion. The larger the angular separation between the laser beams is (the more tilted they are relative to the Z axis), the higher the sensitivity is to in-plane motion, and vice versa for out-of-plane motion. However, larger angular separation also results in the need for larger optical clearance (wider view onto the target) between the measurement point and the 3D LDV. Thus, the optical design of the 3D LDV system is constrained by a tradeoff between sensitivity to in-plane components and spatial constraints (clear optical path and working distance) for the experimental setup and the sample. In the case of 3D LDV system used in this study, the angular separation between the beams, relative to the Z-axis (optical axis), is 6.1 deg (angular separation between any two beams is larger), which means that the sensitivity to in-plane motion components is lower than to out-of-plane ones. This results in the X and Y components having higher noise floor that the Z component, with an increase of 15 – 25 dB and 25 – 30 dB, respectively, as seen in Figure 4 A-C (dashed lines). The acceleration noise floor for all components was increasing with frequency at an approximate rate of 20-25 dB/decade.

The combined effect of the lower promontory response at low frequencies and higher noise floor of the X and Y components, resulted in most of the data (>50%) of the X and Y component being below the acceptable SNR limit for most frequencies below 250 Hz. This is the cause for small (<50Hz wide) gaps in the low frequency data < 250 HZ, as it can be seen in data of the individual components, shown in Figure 4. In case of a missing data for some of the components, the combined velocity was calculated based on the available components only. This was done in order to approximate the trend of the data at the affected frequencies. Overall, these data gaps at low frequencies did not affect any of the observations in this work. On the other side, higher frequency data was available for all motion components, with SNR for the X and Y components of 25 - 40 dB in 0.5-6.5 kHz range, and 5 - 25 dB above 7 kHz. The decrease in SNR at higher frequencies was due to the increasing noise floor with frequency, as well as the decreasing sample response above 7kHz. The LDV signal from the retroreflectors was maintained in the range of 90-100% to maximize SNR for all motion components.

4.3 Effect of stimulation location on promontory motion

Figure 4 A-C indicates that overall the individual orthogonal components exhibited steep notches (“anti-resonances” as termed in Eeg-Olofsson et al., 2013), with a width of less than 1/3 octave and depth of 10-20dB or more. The occurrence and profile of the notches varied between heads, frequencies and stimulation locations. Such notches were more visible in the relative contribution (ratio relative to the combined motion) of each motion component, as shown in Figure 4 D-F. The notches, both in the absolute magnitude and in the relative contribution, appear more extreme (narrower width, deeper depth) for frequency components with lower contribution to the combined motion, such as the Z and Y components at mid and high frequencies in Figures 4 E and F. In contrast, the combined motion indicated a clearer (fewer notches, shallower notch depth, greater width) and more monotonic trend (lower slopes of the magnitude curve), qualitatively similar to curve profiles of BC hearing thresholds in audiometric tests (Stenfelt, 2012; Stenfelt et al., 2004).

Overall the 3D motion of the promontory, indicated in Figure 4 D-F, showed a consistent composition (ratio between individual components), which varied with frequency and stimulation location. At low frequencies (below 500Hz), the out-of-plane (along Z-axis) component was 2 to 14 dB larger than the in-plane (along X and Y axis) components, on average for all stimulation locations. At higher frequencies (above 500Hz) each individual component had a frequency and stimulation location dependence. Specifically, stimulation at location 1 at mid frequencies, 0.7-3 kHz, showed a trend of Z component being largest, with comparable contribution from the X component (anterior-posterior direction) being only 2-3 dB lower on average. Stimulation at location 1 at higher frequencies, above 4 kHz, produced motion with equal contributions from the X and Z components. Mid and high frequency, above 500Hz, stimulation at locations 2 and 3 produced motion with a dominant X component, with a magnitude of 1 to 13 dB larger than that of the Y or Z components, on average. Overall, regardless of stimulation location, the spatial composition of the motion changes at around 500Hz, indicative of the transition between modes of vibration (rigid-body-like motion versus deformation) of the skull, as indicated by previous research (Dobrev et al., 2017).

Based on the data trend in Figure 5 B, it could be hypothesized that stimulation on the thicker sections of the skull (locations 1 and 2), towards the base of the skull (temporal and the occipital bones), improves coupling between the actuator and the cochlear at higher frequencies. The reasoning for this hypothesis is based on results from previous research (Hoyer and Dortheide, 1983; McKnight et al., 2013; Dobrev et al., 2017) that have indicated spatially complex modes shapes of vibrations, for frequencies above 2kHz, of the superior sections of the skull bone, corresponding to thinner bone. Based on that, it could be hypothesized that the thicker sections of the skull, closer to the base, could exhibit qualitatively similar modal behavior, but with higher resonance frequencies, due to their higher mechanical stiffness. This could result in less relative motion, at a given frequency, between the locations 1 or 2 and the cochlea, in comparison to location 3, thus reducing potential loss of energy in the sound propagation path, as demonstrated in previous work (Stenfelt and Goode 2005a; Eeg-Olofsson et al. 2008).

4.4 Transcranial attenuation

Data in Figure 6 indicate that stimulation on location 3 (BAHA location) with the PZTA produces transcranial attenuation similar to the literature (Nolan and Lyon, 1981, Håkansson at al., 1986; Stenfelt, 2012). Stimulation at location 1 has similar behavior to stimulation at location 3 at low and mid frequencies but shows a trend for higher attenuation (average of 12 dB versus 6 dB for location 3) at high frequencies (>4 kHz), suggesting a more selective stimulation. This high-frequency effect has also been observed in previous research in both cadaver heads and patients, illustrated in the data above 5 kHz in Figure 6 of Stenfelt (2012), comparing transcranial attenuation for stimulation at the BAHA location (equivalent to location 3 in the current study) and the mastoid (similar to location 1 in the current study).

Both stimulation locations produce a transcranial gain (negative attenuation) of 2 to 7 dB (95% confidence interval), on average, in the frequency range of 0.1 – 0.5 kHz. Within the nomenclature used in this work, transcranial gain refers to a negative transcranial attenuation, corresponding to the case when the contra-lateral promontory moves more than the ipsi-lateral one. Such a transcranial gain (or negative attenuation) has also been observed in previous research on cadaver heads (Stenfelt and Goode, 2005b) and in some patients (Stenfelt, 2012; Eeg-Olofsson et al., 2011a).

The variability of the transcranial attenuation at low frequencies, in both patients and cadaver heads, could be attributed to the rigid-body-like motion of the head at low frequency (Dobrev et al., 2017). We hypothesize that, for frequencies below its first natural frequency (below 500Hz, more prominently below 250Hz), the head undergoes rigid-body-like motion similar to swaying - combination of translation (of the center of gravity of the head) and rotation of the head with a pivot point (pivot area) at the neck support area, thus such motion should be affected by the stiffness of the neck support.

In the case of experiments on cadaver heads, the head support setups vary, and their stiffnesses have not been well documented. In the case of the head support utilized in the present study, the heads are not firmly connected to the support plate (see Figure 2B), thus resulting in a low torsional stiffness around the anterior-posterior and left-right axes, essentially allowing for the heads to sway relative to their equilibrium vertical position similar to an inverted pendulum. While the quantification of the stiffness requires the measurements of moments and corresponding deflections, we simplify our discussions by looking at only the required moment (countering the restoring force and moment) required to deflect the head away from its equilibrium position. We used this as a proxy for neck stiffness with the assumption that higher restoring moments (units of Nm) will corresponding to higher neck stiffnesses (Nm/deg). In the case of presented experimental setup, the restoring moments against tilting around the horizontal axes (tilt and roll) were limited to <1Nm, and against tilting around the vertical axis (pan) was <0.2Nm. This was due to the limited pretension in the rubber bands in the lateral support structure, which was similar to other experimental setups (McKnight et al., 2013; Dobrev et al., 2017). In the case of living human subjects, the head's vertical orientation is controlled by the neck muscles capable of exerting 10-50 Nm of restoring moment against rotation around the horizontal axes (tilt and roll), and about 15 Nm of restoring moment against rotation around the vertical axes (pan) (Vasavada et al., 2001). This suggests, based on our assumptions, 10-100 higher neck support stiffness in live humans than in commonly used support setups for cadaver head experiments.

Looking at the spatial composition of the low frequency promontory motion, as shown in Figure 4 D-F, data indicates only 3-10 dB lower contributions for the in-plane components (X and Y components), relative to the normal component (Z component) for all stimulation locations below 0.5 kHz. This could be indicative of a significant rotational component of the rigid-body-like motion around the vertical axis (pan) (Dobrev et al., 2017). If the instantaneous axis of rotation, in superior-inferior direction (giving rise to an X component) or anterior-posterior direction (giving rise to a Y component), is closer to the ipsi-lateral side, this could give rise to higher later velocities on the contra-lateral side, thus resulting in larger combined motion on that side, when both in-plane and out-of-plane components are taken into consideration. The assumption for predominance of the rotational motion around the vertical axis (pan) is supported by the potentially lower stiffness in that direction relative to the horizontal axis (tilt and roll) (Vasavada et al., 2001).

4.5 Effect of mastoidectomy on promontory motion

The mastoidectomy seems to affect mostly response due to situation at location 1, specifically around the second resonance peak of PZTA (6-8 kHz), as seen in Figure 7 B. The effect indicated a statistically significant increase in the promontory motion of 2 to 5 dB at 0.5-2kHz ($p<0.05$ in all samples), and a decrease of 10 to 21 dB at 6-8kHz, the latter being statistically significant ($p<0.01$) in only 3 of the 4 samples. However, there was no statistically significant effect of mastoidectomy for stimulation at location 3, which is consistent with measurements in patients indicating no significant change in the air-bone gap (ABG) after similar mastoidectomy procedure (Kim et al., 2010). The magnitude attention for location 1 results in a very similar (mean difference of 0.3 ± 11 dB at 95% confidence interval) magnitude profile (seen in Figure 7A), above 4 kHz, for both stimulation locations, 1 and 3, after mastoidectomy. This could be explained by the potential softening (decrease in impedance), due to the mastoidectomy, of the skull bone structure around location 1, making it more similar in sound transmission properties to the thinner bone structure at location 3. In addition, the mastoidectomy could be potentially lengthening the effective pathway for bone conduction from location 1 to the cochlea due to the removal of the transmission medium (e.g., the mastoid) in-between. The clinically relevant consequence of these observations is that the PZTA could be installed further away from the mastoidectomy (i.e. location 3 instead of location 1) without a major degradation in output level in the measured frequency range. This could be beneficial in medical cases that require the installation of the PZTA in patients with existing mastoidectomy that might be preventing implantation close to the pinna and ear canal.

5 Conclusions

During an initial testing stage, the sound transfer function of a novel subcutaneous bone conduction device (PZTA) have been quantified, and the influence of stimulation location and mastoidectomy have been analyzed based on promontory motion in Thiel-preserved cadaver heads. Future work could include a more detailed examination of the effect of alternative methods for attachment of the PZTA to the skull bone, with the aim of finding a balance between reduced surgical complexity and improvement of efficiency and reliability of the force transfer at the interface between the PZTA and the skull bone.

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Figure Captions

Figure 1. *Different BCHA systems can be divided into different groups by the way of attachment and stimulation of the head (figure based on Reinfeldt et al. 2015).*

Figure 2*. Top and side view of the novel subcutaneous bone conduction PZTA in comparison with a Baha ® Cordelle II actuator.*

Figure 3*. Overview of stimulation positions (A) and head support setup (B). Indicated are the anatomical and 3D LDV coordinate systems on the ipsilateral side. Stimulation positions are: 1) Immediately posterior to pinna; 2) 50-60mm posterior to pinna (same distance as Baha® to ear canal); and 3) Traditional BAHA position. Origin of the 3D LDV coordinate system is situated on the cochlea promontory. Anatomical coordinate*

system axis shown are A (anterior) and S (superior). Corresponding LDV coordinate system axis shown are X (X-axis) and Y (Y-axis).

Figure 4. *Individual components of acceleration of ipsilateral promontory as a function of PZTA stimulation position: A)-C) Magnitudes of orthogonal components of acceleration and combined acceleration for stimulation at positions 1-3; and D-F) Ratio of magnitude of orthogonal components of acceleration relative to the magnitude of the combined acceleration for each stimulation location 1-3; Notes: Bold solid lines are geometric mean of individual motion components, and bold dotted lines are the combined motion, across heads. Thin dotted lines are individual head data. Dashed lines are the mean noise floor, averaged across samples. Note that the combined motion is always larger than any of the individual components.*

Figure 5. *Combined acceleration of ipsilateral promontory as a function of PZTA stimulation location: A) Magnitude of combined acceleration for each stimulation location normalized by the stimulus voltage; and E) Relative magnitude of combined acceleration for stimulation at locations 1 and 2 relative to 3 (BAHA location). Notes: Bold solid lines are geometric mean, across heads, and thin dotted lines are individual head data. An illustration of the stimulation locations on the skull is included in the inset in panel A as a reference.*

Figure 6. *Transcranial attenuation based on promontory motion for PZTA stimulation at locations 1 and 3: A) Combined acceleration of ipsi and contralateral promontory, normalized by the driving voltage; B) Combined motion for contralateral promontory motion relative to corresponding ipsilateral promontory acceleration. Lower values in B) correspond to higher attenuation at the contra- relative to the ipsi-side. Notes: Bold solid lines are geometric mean, across heads, of combined motion component, while thin lines are individual head data. Solid lines with dots in A) represent data for ipsilateral promontory and solid lines without dots represent data for contralateral promontory. Colors indicate the stimulation location.*

Figure 7. *Effect of mastoidectomy on ipsilateral promontory motion for PZTA stimulation on locations 1 and 3: A) Promontory motion data before and after mastoidectomy; B) Response after mastoidectomy relative to the response before mastoidectomy. Notes: Bold lines are geometric mean across heads, while thin lines are combined motion component for individual head data. Solid with dots in A) represent motion data before mastoidectomy, and solid lines without dots represent motion data after mastoidectomy. Colors indicate the stimulation location. An illustration of the approximate location of the mastoidectomy area and the stimulation locations on the skull is included in the inset in panel A as a reference.*